

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/674,653 Confirmation No.: 4786  
Appellants : Marc E. Feinberg  
Filed : September 30, 2003  
For : TISSUE APPROXIMATION DEVICE  
TC/Art Unit : 3773  
Examiner : Melissa K. RYCKMAN  
Docket No. : ETH-5092  
Customer No.: 25570

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**APPEAL BRIEF UNDER 37 C.F.R. §41.37**

Dear Sir:

Responsive to the Rejection mailed April 27, 2011, reopening prosecution, Appellants submitted a second Notice of Appeal on July 27, 2011, and the following Appeal Brief, in combination with a proposed amendment under 37 C.F.R. 41.33(a) to address formal issues.

**1. REAL PARTY IN INTEREST**

The real party in interest is Ethicon, Inc. Route 22 West, Somerville, New Jersey 08876, as evidenced by the assignment recorded at reel 018748, frame 0824.

**2. RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any related appeals or interferences.

**3. STATUS OF CLAIMS**

Claims 3 through 6, 8, 14, 21, 22, and 27 through 50 remain pending in the present application. Claims 5, 6, 8, 38 through 42 and 46 through 48 stand rejected, the rejection of which is hereby appealed. Claims 3, 4, 14, 21, 22, 27-37, 43-45, 49 and 50 are withdrawn as being drawn to non-elected subject matter. Claims 1, 2, 7, 9 through 13, 15 through 20 and 23 through 26 have been canceled.

**4. STATUS OF AMENDMENTS**

Appellants submit on even date herewith a proposed amendment under 37 C.F.R. 41.33(a) to address formal issues raised for the first time in the Office Action of April 27, 2011. The attached claims in the Claim Appendix (8) reflect the amendment.

**5. SUMMARY OF THE CLAIMED SUBJECT MATTER**

Under the provisions of 37 CFR 41.37(c)(1)(v), the following summary of claimed subject matter is made. The summary is in accordance with the rule since the rule does not require any particular format for this section of the Appeal Brief. Note also that the commentary to the rules provides "[a]ppellant may include any other information of record which will aid the Board in considering the subject matter of each independent claim." 69 FR 49976, Comment 53, third column, August 12, 2004.

Claim 8 is directed to a tissue approximation device comprising two elongate arms having proximal and distal ends, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.

The specification and drawings of this application describe and illustrate many embodiments of the tissue approximation device of claim 8. See, e.g., specification at page 4, line 9, through page 12, line 5, and Figures 1-12. Note that Figures 1-5 relate to a parallel forceps embodiment that has been withdrawn from consideration, in response to an election of species requirement, and that Figures 6-12 relate to the elected forceps species.

By way of example only, page 8, line 26 through page 9, line 20 of the specification states:

In the embodiment shown in Figure 6, the tissue approximation device is shown and designated generally by the numeral 100. The approximation forceps 100 have a flexible elongate arm 112, which is interconnected with and substantially similar to a flexible elongate arm 114. Elongate arms 112 and 114 each has a handle 112a and 114a and tong 112b and 114b and may be pivotally connected at attachment means, yoke 116. First and second elongate arms 112,

114 are pivoted in a scissors fashion. Handles 112a and 114a lie on the same plane and have at a proximal end thereof finger grips 118 and 120.

The tongs and adhesive pads interface may be designed to pivot multi directionally by means of a ball and socket mechanism shown in Figures 7 and 8 thus allowing the adhesive pads to conform to various anatomical structures such as a wrist or back. In addition this embodiment provides a means of rotating the adhesive pads with ball and socket 139, 141 to cooperate with yoke 116 allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The multi-directional pivoting motion can be limited by changing the distance from the center point of the ball 131 to surface 133 of adhesive pads 140 or 130 so rotation of the adhesive pads are more parallel to tongs 112b and 114b still allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The ball and socket 139, 141 design includes a slight interference fit allowing the alignment of adhesive pads 130 and 140 with the target anatomical structure and preventing the adhesive pads from flopping around during alignment and application. Preferably, adhesive pads 130, 140 remain parallel to each other and are non-contiguous such that the distance between the adhesive pads 130, 140 allows access to the wound for application of a permanent wound closure means.

As explained at page 11, lines 26-28, with the tissue approximation device of the present invention, a wound may be approximated without substantially evert the edge surfaces of the wound, during application of the wound closure means.

Claim 38 is directed to a tissue approximation device for application to a skin surface adjacent to a wound, comprising: a pair of arms, each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector; an attachment mechanism coupled to each arm that movably couples the arms to each other so that a distance between each tong is selectively variable; an adhesive pad removably coupled to the connector of each tong, wherein each adhesive pad has an adhesive surface that extends in a plane generally parallel to the longitudinal axis of the respective tong, the adhesive surface having a high shear resistance for holding the skin

surface and a low peel resistance for removal from the skin surface, and wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound; and a locking mechanism coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other, wherein the coupling is rotatable and connects the adhesive pad to the tong so as to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis and the connector is one of a ball and a socket and the adhesive pad includes the other of the ball and the socket, wherein the ball and socket are snap fit together in an interference fit.

The specification and drawings of this application describe and illustrate many embodiments of the tissue approximation device of claim 38. See, e.g., specification at page 4, line 9, through page 12, line 5, and Figures 1-12. Note that Figures 1-5 relate to a parallel forceps embodiment that has been withdrawn from consideration, in response to an election of species requirement, and that Figures 6-12 relate to the elected forceps species.

By way of example only, page 8, line 26 through page 9, line 20 of the specification states:

In the embodiment shown in Figure 6, the tissue approximation device is shown and designated generally by the numeral 100. The approximation forceps 100 have a flexible elongate arm 112, which is interconnected with and substantially similar to a flexible elongate arm 114. Elongate arms 112 and 114 each has a handle 112a and 114a and tong 112b and 114b and may be pivotally connected at attachment means, yoke 116. First and second elongate arms 112, 114 are pivoted in a scissors fashion. Handles 112a and 114a lie on the same plane and have at a proximal end thereof finger grips 118 and 120.

The tongs and adhesive pads interface may be designed to pivot multi directionally by means of a ball and socket mechanism shown in Figures 7 and 8 thus allowing the adhesive pads to conform to

various anatomical structures such as a wrist or back. In addition this embodiment provides a means of rotating the adhesive pads with ball and socket 139, 141 to cooperate with yoke 116 allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The multi-directional pivoting motion can be limited by changing the distance from the center point of the ball 131 to surface 133 of adhesive pads 140 or 130 so rotation of the adhesive pads are more parallel to tongs 112b and 114b still allowing adhesive pads 130 and 140 to remain parallel to each other during wound approximation. The ball and socket 139, 141 design includes a slight interference fit allowing the alignment of adhesive pads 130 and 140 with the target anatomical structure and preventing the adhesive pads from flopping around during alignment and application. Preferably, adhesive pads 130, 140 remain parallel to each other and are non-contiguous such that the distance between the adhesive pads 130, 140 allows access to the wound for application of a permanent wound closure means.

A snap fit connection between the ball and socket of the ball and socket joint is explained at page 9, lines 23-25, wherein Appellants disclose that the sockets have flex arms 121, 122 (Figs. 7 and 8) which deflect when the balls 131, 141 are installed.

As explained at page 11, lines 26-28, with the tissue approximation device of the present invention, a wound may be approximated without substantially evertting the edge surfaces of the wound, during application of the wound closure means.

## 6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- I. Claim 38-42 stand rejected under 35 U.S.C. §112, first paragraph as exceeding the scope of enablement provided by the specification.
- II. Claims 5, 6, 8, and 46 through 48 stand rejected under 35 U.S.C. §103(a) as obvious over Hasson, U.S. Patent No. 4,724,838, in view of Taylor et al., U.S. Patent No. 6,394,951.

7. ARGUMENT

*The Present Invention*

The present invention is directed to a tissue approximation device. The claimed tissue approximation device includes two elongate arms having proximal and distal ends, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.

*The Relied-upon References*

Hasson discloses a forceps-type surgical instrument which includes a pair of forceps blades coupled together at their proximal ends and spreadable and closable at their distal ends. A pair of feet are respectively mounted on the distal ends of the blades and extend transversely outwardly of the blades to enlarge the working area of the blades and to facilitate the application of counter-pressures during surgical operations. At least one aperture is formed through at least one of the feet for receiving and guiding a needle, suture or the like therethrough at a point offset from the plane of the forceps blades.

According to Hasson, an object of the invention is to provide a new and improved forceps-type surgical instrument which can be used for various tissue manipulations, the instrument being capable of delicately holding, restraining and stabilizing tissues by external or internal counter-pressure without requiring tissue grasping. In the exemplary embodiment of the invention, the forceps-type surgical instrument includes a pair of forceps blades coupled together at their proximal ends and spreadable and closable at their distal ends. The forceps blades may be incorporated in simple spring-loaded V-shaped configurations of different designs, such as straight, angular or offset, or take the shape of a bayonet. In another embodiment, the blades also may be incorporated in a hinged or pivoted scissors-like instrument.

This latter embodiment is illustrated in Fig. 7, which illustrates a scissors-type forceps including blades 54 hinged or pivoted, as at 56, intermediate the distal ends 58 and proximal ends 60 thereof, and feet 24 provided on the tips of distal ends 58. The feet may be mounted to the distal ends 58 of blades 54 by means of jointed constructions, such as ball-and-socket constructions as shown in Fig. 14 (col. 4, line 53, bridging to col. 5, line 9). In this embodiment (Fig. 14), a ball 301 is mounted on the end of blade 12 with a socket 302 mounted on the stub 303 of a blade fixed to the foot 34 (col. 5, lines 11-13).

Taylor et al. propose methods and devices that a surgeon may use to stabilize a beating heart during a surgical procedure on the heart. As proposed, a stabilizing device is introduced through an opening in the chest and brought into contact with the beating heart. By contacting the heart with the device and by exerting a stabilizing force on the device, the motion of the heart caused by the contraction of the heart muscles is effectively eliminated such that the heart is stabilized and the site of the surgery is said to move only minimally, if at all.

As proposed by Taylor et al., in separate steps, the surgeon contacts the heart with the stabilizing device, assesses the degree of movement of the anastomosis site, and exerts a force on the stabilizing device such that the contraction of the beating heart causes only minimal excess motion at the surgery site. By fixing the position of the stabilizing device in a configuration where the motion of the beating heart is effectively eliminated, the surgeon is able to stabilize the beating heart for the duration of the procedure. The stabilizing device may be attached to a rigid support or may be attached to a semi-rigid support which is rendered motionless mechanically, chemically, or by human intervention. In certain preferred embodiments, the stabilizing device is affixed to a semi-rigid support which is caused to become rigid, by any of a variety of techniques, such that the position of the stabilizing device becomes fixed by the support, and the heart remains substantially motionless for the duration of the procedure.

### ***The Rejections***

#### **I. Claim 38-42 stand rejected under 35 U.S.C. §112, first paragraph as exceeding the scope of enablement provided by the specification.**

At page 3 of the final Office Action, the Examiner indicates:

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Line 17 of Claim 38 states "the connector is a rotatable connector", the current specification and current drawing do not enable this, the connector as shown in the drawings, is element 139 in Fig. 7, element 139 does not rotate as it is fixed to arm.

Appellants submit that their amendment under 37 C.F.R. 41.33(a) moots this basis for rejection and renders these claims allowable, since they have not

been rejected over prior art. Reversal of this rejection is courteously solicited in view thereof.

**II. Claims 5, 6, 8, and 46 through 48 stand rejected under 35 U.S.C. §103(a) as obvious over Hasson, U.S. Patent No. 4,724,838, in view of Taylor et al., U.S. Patent No. 6,394,951.**

**a. Separate argument of claim 8**

**i. Claim construction**

In construing claim limitations it must be kept in mind that "as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). [Emphasis added].

Here, claim 8 requires that the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other. This is described at page 9, lines 17-20, and 28-30, describing Fig. 8, which is reproduced below in pertinent part.

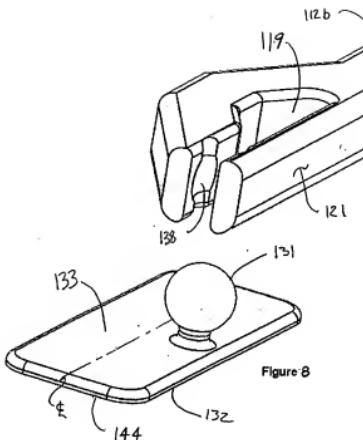


Figure 8

At page 9, lines 28-30, Appellants state:

When adhesive pad 140 or 130 [Figs. 6 and 7] the ball 131 are offset from the centerline of surface 133 as shown in FIG. 8, clearance between the tongs is increased and tissue eversion may be controlled during approximation.

The Board should note that the ball 131 is offset in the medial direction of the tongs from the centerline, resulting in the medial edges of the pads being prevented from meeting (i.e. "non-contiguous") when the apparatus is in the closed position,

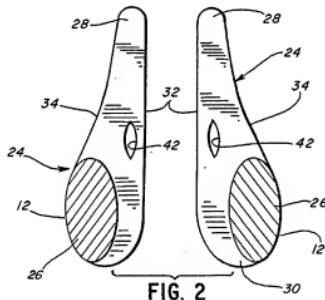
...such that the distance between the adhesive pads 130, 140 allows access to the wound for application of a permanent wound closure means. [Page 9, lines 18-20].

## ii. Analysis

The Examiner has committed legal and factual error in taking the following position with respect to independent claim 8:

Regarding Claims 8 and 46, Hasson teaches a tissue approximation device comprising two elongate arms (54, Fig. 7), an attachment means (56) to secure the elongate arms to each other at one or more locations, pads (24, pad is defined in the World English Dictionary as any of various level surfaces of flat-topped structures) movably connected (move via the ball and socket (301, 302, Fig. 14) on at least a portion of the elongate arms to anchor the tissue approximation device to the tissue, and a locking means (64) to lock the elongate arms in place relative to each other, wherein (i) the pads are spaced apart from the one or more locations of the attachment means (56) in the direction of the elongate arms (the pads 24 are spaced apart from 56 in the direction of the arms), and (ii) the tissue approximation device has an open (when moving 62 it opens and closes, Fig. 7) and a closed position, and when in the closed position, the pads are parallel and non-contiguous to each other (fig. 7, the pads are not touching when closed). [Emphasis added].

The configuration of the Hasson feet ("pads") 24 to the distal ends 58 of the blades ("elongate arms") 54 is better shown in Fig. 2, reproduced below,



and Hasson explains:

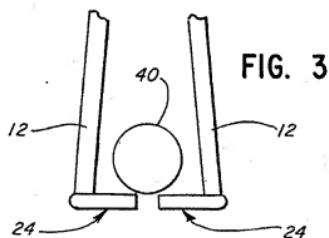
In the embodiment illustrated in FIGS. 1 and 2, feet 24 are mounted to the distal ends 26 of forceps blades 12 close to or at the lateral edges and posterior tip of the feet to allow the instrument to function as a tubal forceps, as described hereinafter, by restraining and stabilizing a tube-like structure or organ between the medial edges 32. Medial edges 32 are serrated, as at 36 (FIG.

- 1) to facilitate the holding of sutures or less delicate tissues and to make the holding or grasping more secure and less tenuous. [Col. 3, lines 34-40; emphasis added].

Thus, it is clear that the positioning of the Hasson feet is quite the opposite of the presently disclosed embodiment, discussed above, since the distal ends of the Hasson forceps blades are attached at the lateral edges of the feet, instead of toward the medial edges, thus biasing the medial edges together. This difference results in the Hasson device being designed such that the medial edges of the feet actually come into contact when it is closed, and as such the edges of the feet are contiguous when closed, in contrast to the limitations of present claim 8, and contrary to the Examiner's finding, highlighted in the quotation above.

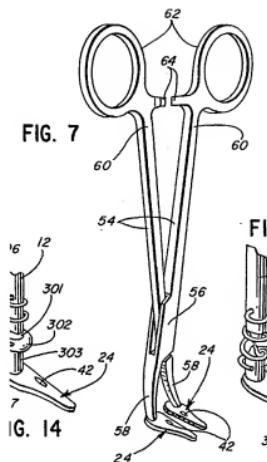
In further support, Hasson explains:

FIG. 3 shows, somewhat schematically, the inward projection of feet 24 relative to forceps blades 12 for closing beneath a tubular structure 40 for purposes of gently lifting or stabilizing the structure. [Col. 3, lines 56-59; emphasis added].



**FIG. 3**

Accordingly, Appellants submit that the Examiner's interpretation of the device of Hasson's Fig. 7 as indicating the feet are "not touching when closed" constitutes a factual error in reference interpretation. Figure 7 is reproduced below.



Notably, Fig. 7 of Hasson illustrates the forceps device is not entirely closed, as evidenced by the gap between the edges of lock means 64, and contrary to the Examiner's assertion.

Clearly, Hasson fails to disclose or suggest each and every claim limitation.

Additionally, the Examiner's position constitutes legal error, in that the Examiner has failed to consider the reference teachings as a whole, as required by the patent law.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). **MPEP 2141.03 VI. [Emphasis added]**.

As discussed above, Hasson actually discloses that the forceps device thereof is designed such that the feet can close beneath a tubular structure [col. 3, lines 56-59]. Hasson never discloses or even suggests that the medial edges of the feet thereof should be non-contiguous (i.e. "not touching") when the forceps device is closed. In fact, even in the abstract Hasson indicates that the device is "closable at [its] distal [end]". In this regard, Hasson effectively teaches away from the claimed invention.

An applicant may rebut a *prima facie* case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect. *In re Geisler*, 116 F.3d at 1469, 43 USPQ2d at 1365 (Fed. Cir. 1997).

Nor would it have been obvious to modify the Hasson device in the manner of claim 8, since to do so would eliminate the ability of the device to lift tubular structures (e.g. veins, arteries, etc.), contrary to the discussion of Fig. 3, quoted above.

If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

The Examiner turns to Taylor et al. for a suggestion that the feet of Hasson could be equipped with adhesive pads.

Hasson teaches the claimed invention but fails to specify the pad being an adhesive pad. However, Taylor teaches using an adhesive surface (col. 14, II. 15-17). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adhesive surface of Taylor with the pads of Hasson, as the adhesive aids in securing the device during the procedure. [Office Action, page 4].

Even assuming, *arguendo*, that the Examiner is correct (with which Appellants do not agree), it is abundantly clear that Taylor et al. is insufficient to

cure the underlying deficiencies of Hasson, explained above. Taylor et al. do not appear to disclose or suggest that the "friction means" (feet) thereof should be configured to be non-contiguous when their device is closed, as claimed herein.

Accordingly, even if combined according to the Examiner's suggestion, the references fail to disclose or suggest each and every claim limitation, and cannot therefore establish a *prima facie* case of obviousness.

When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)). *In re Wada and Murphy*, BPAI Appeal 2007-3733.

Reversal of this rejection of claim 8, and all claims dependent thereon is courteously solicited on these bases.

**b. Separate argument of claims 5 and 6**

Solely for the purpose of this appeal, claims 5 and 6 will not be separately argued and will stand or fall with claim 8.

Reversal of the rejection is courteously solicited.

**c. Separate argument of claim 46**

**i. Claim construction**

In construing claim limitations it must be kept in mind that "as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). [Emphasis added].

Here, claim 46 requires that the adhesive pad have a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector (claim 8), wherein the second surface has the socket and the distal end (of the elongate arm) has the ball. [Emphasis added]. This is illustrated in Figs. 6-8 and explained at page 4, lines 29-31.

**ii. Analysis**

The Examiner has committed factual and legal error in taking the following position with respect to dependent claim 46:

Regarding Claims 8 and 46, Hasson teaches a tissue approximation device comprising two elongate arms (54, Fig. 7), an attachment means (56) to secure the elongate arms to each other at one or more locations, pads (24, pad is defined in the World English Dictionary as any of various level surfaces of flat-topped structures) movably connected (move via the ball and socket (301, 302, Fig. 14) on at least a portion of the elongate arms... The pad has a second surface that is rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector (301,302, col. 5, ll. 11,12), wherein the second surface [h]as a socket (302) and the distal end of the elongate arms has a ball (301), the pad is

rotatable about the ball and socket connector about at least two axes (col. 5, ll. 15-18). [Office Action, pages 3-4; emphasis added].

While not specifically disclosed by Hasson, the feet 24 thereof clearly have first (bottom) and second (top) surfaces. Figure 14 cited by the Examiner is reproduced below.

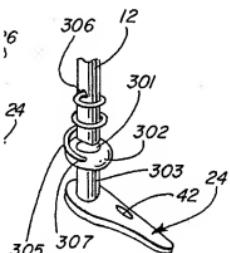


FIG. 14

Even from this Figure, it is clear that the socket 302 is not disposed on the top (second) surface of foot 24, but is instead offset from the surface by a stub 303. Likewise, a full and fair reading of Hasson reveals that

[i]n FIG. 14 a ball 301 is mounted on the end of blade 12 with a socket 302 mounted on the stub 303 of a blade fixed to the foot 34.

Thus, the Examiner's assertion is without merit, constituting factual error as to the position of the socket, and legal error since it is clear that Hasson, even in combination with Taylor et al., fails to disclose each and every limitation of claim 46. No *prima facie* case of obviousness has been established. *In re Wada and Murphy*, BPAI Appeal 2007-3733.

Reversal of this rejection of claim 46 is courteously solicited on these bases.

**d. Separate argument of claim 47**

**i. Claim construction**

In construing claim limitations it must be kept in mind that "as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). [Emphasis added].

Here, claim 47 requires that the adhesive pad have a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector (claim 8), wherein the second surface has the ball and the distal end (of the elongate arm) has the socket. [Emphasis added]. This is illustrated in Fig. 12 and explained at page 4, lines 26-29.

**ii. Analysis**

The Examiner has committed legal error in taking the following position with respect to dependent claim 47:

Regarding claim 47, Hasson teaches the claimed invention including a ball and socket connector, however does not specify the second surface has the ball and the distal end has the socket. It would have been obvious to one having ordinary skill in the art at the time the invention was made to rearrange the device to have the second surface have the socket and the distal end have the ball, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. [Office Action, page 5; emphasis added].

As discussed above, Figure 14 of Hasson fails to illustrate an embodiment wherein the socket portion of a ball and socket coupler is disposed on the top (second) surface of foot 24. Instead, the socket is offset from the top surface of the foot 24 by stub 303. Mere rearrangement of the Hasson device, as suggested by the Examiner, would result in the ball 301 being disposed on the upper end of stub 303, and not on the surface of foot 24.

Accordingly, even if modified in the manner suggested by the Examiner, the prior art would not meet each and every limitation of claim 47, as required by the patent law. *No prima facie case of obviousness can be established. In re Wada and Murphy, Id.*

Additionally, it is improper to rely on case law, *per se*, to support a case of obviousness. Such reliance constitutes legal error.

[T]he examiner incorrectly drew from *Durden*, a case turning on specific facts, a general obviousness rule...Mere citation of [case law] as a basis for rejecting process claims that differ from the prior art by their use of different starting materials is improper, as it sidesteps the fact-intensive inquiry mandated by section 103... This method of analysis is founded on legal error because it substitutes supposed per se rules for the particularized inquiry required by section 103. In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995). [Emphasis added].

Reversal of this rejection of claim 47 is courteously solicited on these bases.

**e. Separate argument of claim 48**

**i. Claim construction**

In construing claim limitations it must be kept in mind that "as an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). [Emphasis added].

Here, claim 48 requires that the second surface and the distal end of the elongate arm connect in a snap fit manner. This is illustrated in Figs. 7 and 8, and explained at page 9, lines 23-25.

**ii. Analysis**

The Examiner has committed factual and legal error in taking the following position with respect to dependent claim 48:

Regarding Claim 48, Hasson teaches the second surface and the distal end of the elongate arm connect in a snap fit manner (col. 5, ll. 11-18).

Appellants submit that Hasson is silent as to snap fitting. At the portion of Hasson cited by the Examiner, the patentee states:

In FIG. 14 a ball 301 is mounted on the end of blade 12 with a socket 302 mounted on the stub 303 of a blade fixed to the foot 34. Optionally a coil spring 305 could be anchored at one end 306 to the blade 12 and at the other end 307 to the socket 302 in such a way as to orient the foot 34 as hereinbefore described. However,

the foot can be articulated in any appropriate direction to accommodate the foot to the surface of the tissue being sutured. [Col. 5, lines 11-20].

This portion of Hasson describes the ball and socket joint, but fails to indicate that the socket is flexible so as to permit the ball to be merely snapped into place. Hasson clearly fails to disclose sockets as illustrated in the present specification, which have flex arms 121, 122 (Figs. 7 and 8) which deflect when the balls 131, 141 are installed (specification, page 9, lines 23-25).

The Examiner appears to be relying on inherency as to the ability of a ball and socket joint to be snap fit together. As the Board well-knows, inherency must be certain, and cannot rely on optimization of prior art conditions.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); **MPER 2112 (IV).** [Emphasis added].

Hasson is entirely silent as to any particular socket design, and the illustration in Figure 14 (item 302) is only schematic, such that the specific design is not apparent.

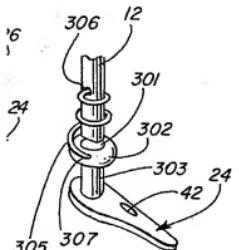


FIG. 14

Further, the only indication as to materials of construction of the Hasson device is set forth at column 3, lines 8-10, wherein patentee discloses that the blades can be made of "metal or like material". If the same is true of the ball (at the end of the blades) and socket joint, one skilled in the art would recognize that a metal ball and socket joint usually necessitates heating of the socket so as to expand it sufficiently to permit insertion of the ball, since the upper circumference of the socket surrounds the upper circumference of the ball. Thus, the socket portion of Hasson is not necessarily flexible enough to permit a snap fit insertion of the ball.

Accordingly, Appellants submit that the Examiner has factually erred, in that Hasson fails to disclose a snap fit ball and socket joint, and legally erred by apparently assuming that all ball and socket joints are inherently snap fittable.

Reversal of this rejection of claim 48 is courteously solicited on these bases.

In summary, nowhere does Hasson disclose or suggest that the feet 24 are parallel and non-contiguous to each other when the forceps are in the closed position; nor that the feet 24 extend in a plane generally parallel to the longitudinal axis of the respective blades; nor that the feet 24 include the other of the ball and the socket joint 301, 302; nor that the ball and socket are snap fit together in an interference fit, as claimed herein. Taylor et al. fails to cure these deficiencies of Hasson.

#### ***Additional Comments***

As noted in section I above, the Examiner has failed to reject claims 38-42 over prior art. However, the Examiner has also failed to indicate the allowability of these claims in the event the formal rejection is successfully addressed. In the event the Examiner amends the rejections so as to reject claims 38-42 over

Hasson in view of Taylor et al. in her Answer, Appellants pose the following arguments.

Claim 38 requires several elements not addressed by the combination of Hasson and Taylor et al.: (1) that the adhesive pads have adhesive surfaces which extend in a plane generally parallel to the longitudinal axis of their respective tong; (2) that the adhesive pad includes one of the ball or socket of a ball and socket joint; and (3) that the ball and socket are snap fit together in an interference fit.

With respect to distinctions (2) and (3), Appellants reiterate their comments with respect to the rejections of claims 46-48 above, which contain quite similar limitations. As to distinction (1), neither of Hasson or Taylor et al. disclose or suggest this limitation, and cannot therefore establish a *prima facie* case of obviousness as to the present claims.

Solely for the purpose of this appeal, claims 39-42 will not be separately argued and will stand or fall with claim 38.

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The Board of Appeals is respectfully requested to remand this application to the Examiner with a direction to allow the claims.

Respectfully submitted,

Date: September 27, 2011



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**8. CLAIMS APPENDIX**

5. The tissue approximation device of claim 8, where the elongate arms form a pair of forceps, the attachment means is a yoke on the forceps, and the locking means is a ratchet mechanism on the forceps.
6. The tissue approximation device of claim 5, where the distance between the elongate arms is adjustable by means of a ratchet mechanism.
8. A tissue approximation device comprising two elongate arms having proximal and distal ends, an attachment means to secure the elongate arms to each other at one or more locations, adhesive pads movably connected on the ends of the elongate arms to anchor the tissue approximation device to the skin, and a locking means to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means in the direction of the elongate arms, and (ii) the tissue approximation device has an open and a closed position, and when in the closed position, the adhesive pads are parallel and non-contiguous to each other, where the adhesive pad has a first adhering surface and a second surface rotatably coupled to the distal end of each of the elongate arms by a ball and socket connector, wherein the second surface has one of a socket and a ball that communicates with the other one of a ball and a socket on the distal end of each of the elongate arms, and the adhesive pad is rotatable around the ball and socket connector about at least two axes.
38. A tissue approximation device for application to a skin surface adjacent to a wound, comprising:
  - a pair of arms, each arm having a longitudinal axis and opposed ends, wherein one end includes a handle and the other end includes a tong with a connector;

an attachment mechanism coupled to each arm that movably couples the arms to each other so that a distance between each tong is selectively variable;

an adhesive pad removably coupled to the connector of each tong, wherein each adhesive pad has an adhesive surface that extends in a plane generally parallel to the longitudinal axis of the respective tong, the adhesive surface having a high shear resistance for holding the skin surface and a low peel resistance for removal from the skin surface, and wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of the wound and conform to the skin surface adjacent to the wound; and

a locking mechanism coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other,

wherein the coupling is rotatable and connects the adhesive pad to the tong so as to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis and the connector is one of a ball and a socket and the adhesive pad includes the other of the ball and the socket, wherein the ball and socket are snap fit together in an interference fit.

39. The device of claim 38, wherein the arms are connected in a scissors configuration.

40. The device of claim 38, wherein the adhesive pad includes serrations that provide flexibility to the adhesive surface.

41. The device of claim 38, wherein the locking mechanism includes a ratchet.

42. The device of claim 38, wherein the arms are made of a resilient material.

46. The device of claim 8, wherein the second surface has the socket and the distal end has the ball.

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47. The device of claim 8, wherein the second surface has the ball and the distal end has the socket.

48. The device of claim 8, wherein the second surface and the distal end of the elongate arm connect in a snap fit manner.

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**9. EVIDENCE APPENDIX**

None.

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**10. RELATED PROCEEDINGS APPENDIX**

None.